

### ***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 35-67 are pending in the application, with claim 35 being the independent claim. New claims 36-67 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested. Support for these changes is found in the claims as originally filed and throughout the application.

The specification has been amended merely to correct obvious typographical errors. Not only would one skilled in the art recognize the existence of the errors, but the appropriate corrections as well. As such, these changes add no new matter. *See* MPEP § 2163.07.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

### ***Rejections under 35 U.S.C. § 102***

#### ***1. § 102(b) Rejections***

The Examiner rejected claim 35 under 35 U.S.C. § 102(b) as allegedly being anticipated by any one of Gugger *et al.* (U.S. Patent No. 6,033,714, hereinafter "Gugger"), Chaihorsky (U.S. Patent No. 5,670,632, hereinafter "Chaihorsky") or Obata *et al.* (Japanese Patent No. 7-173148, hereinafter "Obata"). Applicants respectfully traverse this rejection.

The Examiner stated that Gugger, Chaihorsky and Obata "disclose a product comprising a high purity isoflavone enriched product as called for in the instant claims." (*See* the Office Action at 2.)

Solely in an effort to expedite prosecution, Applicants have amended the claims so that the required purity of the isoflavone enriched fraction is greater than about 70%. None of Gugger, Chaihorsky or Obata teach an isoflavone enriched fraction obtained by a process comprising two chromatography steps, wherein the resulting purity immediately following the secondary chromatography step is greater than 70%. At best,

Gugger teaches a purity level of 20%-50% following chromatography. (*See* Gugger, col. 5, line 63 through col. 6, line 3.) Chaihorsky likewise teaches a purity level of no greater than about 50%. (*See* Chaihorsky, col. 7, lines 5-9.) Obata teaches a procedure of purifying genistein. However, no level of purity is disclosed. The purity level obtained by the process of the instant invention is significantly higher and is well beyond the expected purity obtained by the process of Gugger, Chaihorsky or Obata.

The purity level of the isoflavone enriched fraction is a result of the process employing both a primary and secondary chromatography step. None of the references teach such a process. Moreover, even if more than one chromatography step was performed, the cited processes are not comparable to that of the instant invention. The primary and secondary chromatography steps of the instant claims are performed using different chromatography resins, which will ensure that additional impurities are removed from the isoflavone composition. If more than one step using the same chromatography resin is performed, a high purity product would not be obtained. In addition, the elution system employed by the present invention uses a solvent gradient, while the elution systems of Gugger, Chaihorsky and Obata employ a single solvent.

Furthermore, the chromatography resins used by Chaihorsky and Obata are different than those used in the instant invention. For example, the cationic resins of Chaihorsky all have a sulfonic acid functional group, such as DOWEX® MSC-1, which are not employed by the instant invention. Chaihorsky's use of highly polar cation exchange resins differs from the use of the resins of the instant invention, which employ hydrophobic interaction as a means of achieving separation of isoflavones. Obata employs a one step chromatographic procedure using the activated synthetic resin Diaion HP-20.

Although Gugger does employ a hydrophobic resin, it was found by the inventors that a particular macroporous hydrophobic resin with certain pore size distribution and composition out-performed other resins. Specifically, the divinylbenzene content of the resin is expected to be important for obtaining the isoflavone enriched fraction of the invention in the Gugger process.

In view of the above, it is clear that claim 35 is not anticipated by Gugger, Chaihorsky or Obata. Applicants therefore respectfully submit that this rejection is in error and should be withdrawn.

## **2. § 102(a) Rejections**

The Examiner further rejected claim 35 under 35 U.S.C. § 102(a) as allegedly being anticipated by Katayama *et al.* (Japanese Patent No. 2002-80474, hereinafter "Katayama") or Izumi *et al.* (JP 2002-3487, hereinafter "Izumi"). Applicants respectfully traverse this rejection.

The Examiner stated that Katayama and Izumi "disclose a product comprising a high purity isoflavone enriched product as called for in the instant claims." (*See* the Office Action at 2.)

There are a number of technical differences between the applied Japanese patents and the claimed invention. However, in the interest of expediting prosecution, Applicants have herewith filed a Declaration under 37 C.F.R. § 1.131 to "swear behind" the Katayama and Izumi references. Accordingly, Applicants respectively assert that this rejection should be reconsidered and withdrawn. Therefore, claim 35 should be found allowable.

## **3. § 102(e) Rejections**

The Examiner further rejected claim 35 under 35 U.S.C. § 102(e) as allegedly being anticipated by Kozak *et al.* (U.S. Patent No. 6,517,840, hereinafter "Kozak") or Fujikawa *et al.* (U.S. Patent No. 6,479,054, hereinafter "Fujikawa"). Applicants respectfully traverse this rejection.

The Examiner stated that Kozak and Fujikawa "disclose a product comprising a high purity isoflavone enriched product as called for in the instant claims." (*See* the Office Action at 3.)

Solely in an effort to expedite prosecution, Applicants have amended the claims so that the required purity of the isoflavone enriched fraction is greater than about 70%. Neither Kozak nor Fujikawa teach an isoflavone enriched fraction obtained by a process comprising two chromatography steps, wherein the resulting purity immediately following the secondary chromatography step is greater than 70%. At best, Kozak teaches a purity level of at most about 72% (*see* Table 9), with most experimental results being between 20% and 60% (*see* Table 2). Furthermore, Kozak does not teach a chromatography step at all. (*See* Kozak, col. 5, line 14 through col. 6, line 7.)

Fujikawa teaches only the isolation of the isoflavone genistin. (*See* Fujikawa, col. 3, lines 52-55.) Furthermore, while Fujikawa discloses compositions having a high purity, the purity is not greater than 70% immediately following a secondary chromatography step.

The purity level of the isoflavone enriched fraction is a result of the process employing both a primary and secondary chromatography step. Neither of the references teach such a process. The cited processes are not comparable to that of the instant invention. The primary and secondary chromatography steps of the instant claims are performed using different chromatography resins, which will ensure that additional impurities are removed from the isoflavone composition. If more than one step using the same chromatography resin is performed, a high purity product would not be obtained immediately after the chromatography steps. Additional steps of centrifugation and removal of the solvent, as performed by Fujikawa, would be necessary. The instant invention is directed to a composition with purity of greater than 70% immediately following a secondary chromatography step. Fujikawa does not disclose any level of purity immediately after chromatography; the isoflavone fraction of Fujikawa must have additional steps performed upon it after the single chromatographic step in order to increase the purity of the isoflavone composition. In addition, the elution system employed by the present invention uses a solvent gradient, while the elution system of Fujikawa employs a single solvent.

Furthermore, the chromatography resin used by Fujikawa is different than those used in the instant invention. Fujikawa employs a one step chromatographic procedure using the activated synthetic resin Diaion HP-20.

In view of the above, it is clear that claim 35 is not anticipated by Kozak or Fujikawa. Applicants therefore respectfully submit that this rejection is in error and should be withdrawn.

### ***Conclusion***

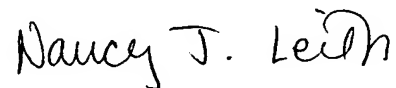
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be

withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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